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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,875	08/07/2001	Hiromu Ohnogi	OHNOGI=1	9130

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EXAMINER

HUI, SAN MING R

ART UNIT PAPER NUMBER

1617

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/890,875

Applicant(s)

OHNOGI ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 25, 2002 has been entered.

Applicant's amendments filed October 25, 2002 have been entered.

The cancellation of claims 4 and 5 in amendments filed October 25, 2002 is acknowledged.

The outstanding rejections under 35 USC 112, first and second paragraph have been withdrawn in view of the amendments filed October 25, 2002.

The outstanding double patenting rejection is withdrawn in view of the cancellation of claims 4 and 5.

Claims 6-8 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression, "a method of treating or preventing hepatitis" in claim 7, line 2, renders the claims indefinite as failing to clearly set forth the metes and bounds of the patent protection desired. Examples of how and when to prevent hepatitis are not set forth in the specification. Absent such exemplification, the skilled artisan could not establish the identity of those situations wherein prevention of hepatitis would be effected. Furthermore, it is unclear as to the degree of prevention (e.g., total prevention, some prevention, probable prevention, total prevention in most cases...etc.) herein because the specification does not disclose the extent of prevention achieved.

The term "severe hepatitis" in claim 7 is a relative term which renders the claim indefinite. The term "severe hepatitis" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what condition would be considered "severe".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koyama et al (EP 0 984 001) and Rousset et al. (Proc. Natl. Acad. Sci. USA, 1992; 89 :1890-1893).

Koyama et al. teaches the compounds of Formula II herein as useful to enhance the production of interleukin-10 (See page 13, line 9; also page 15, paragraph 0091). Koyama et al. teaches the dosage of the compounds herein to be 0.1 μ g – 100mg/kg/day (See page 13, line 23). Koyama et al. also teaches that the compounds can be administered orally and can be incorporated into food and/or beverage (See page 13, line 32-33). Koyama et al. also teaches the compounds therein, which encompass the instant compounds of Formula II, are useful in treating hepatitis viral infection (See page 17, paragraphs 0107 and 0108).

Rousset et al. teaches interleukin-10 is B-cell growth factor (See abstract, also page 1891, col.1, Result Section).

Koyama et al. does not expressly teach the method of employing the instant compounds specifically for enhancing the production of growth factor and treating the herein claimed diseases thereby.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the specific compounds of Formula II herein, in the method of enhancing the production of B-cell growth factor; thereby treating diseases treatable with the enhanced production of B-cell growth factor such as hepatitis.

One of ordinary skill in the art would have been motivated to employ the specific herein claimed compounds of Formula II, in the method of enhancing the production of

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B-cell growth factor and thereby treating diseases treatable with the enhanced production of B-cell growth factor such as hepatitis. Possessing the teachings of the cited prior art, one of ordinary skill in the art would have been reasonably expected to employ any compounds of Koyama et al., including the compounds of Formula (II) herein, to enhance the production of B-cell growth factor and thereby treating diseases treatable with the enhanced production of B-cell growth factor such as hepatitis. Please note that the cited prior art teaches the ultimate use of the old and well-known compounds claimed herein: a method of treating hepatitis employing the herein claimed compounds.

Response to Arguments

Applicant's arguments with respect to claims 6-8 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
January 9, 2003


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200